

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JAZZ PHARMACEUTICALS, INC. and
JAZZ PHARMACEUTICALS IRELAND
LIMITED,

Plaintiffs,

v.

ROXANE LABORATORIES, INC.

Defendant.

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) Civil Action No. 2:15-cv-01360 (ES)(JAD)
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**ROXANE LABORATORIES, INC.'S
RESPONSIVE *MARKMAN* BRIEF
IN SUPPORT OF ITS CLAIM CONSTRUCTIONS**

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I. INTRODUCTION

On November 14, 2016, Jazz advised Roxane that it was dropping its infringement claims regarding the '203 patent and therefore would not be including in its responsive *Markman* brief arguments regarding the claim terms (“admixing” and “contacting”) previously at issue in that patent. For that reason, Roxane also is not including responsive arguments for those claim terms. Hence, the only claim term remaining for the Court to construe is “concomitant.”

Jazz’s proposed construction for “concomitant” is improper for at least two reasons. First, Jazz’s proposed definition defies black-letter law holding that the inventor may act as his own lexicographer. Here, the inventor did just that by providing a special definition for “concomitant” when the two drugs at issue are GHB and valproate; but instead of respecting the inventor’s construction, Jazz truncates it for litigation purposes—a transparent ploy that is not permissible.

Second, Jazz’s construction violates the purpose of claim construction, which is to provide clarity to the meaning of claim terms. Jazz’s proposed construction requires determining the time period in which the effects of the first drug “are still operative in the patient” without explaining what that means or how a POSA would even begin to determine that. Jazz’s construction thus imports vagueness into a claim term where none is needed because the inventor already provided a definitive construction in the specification for the claimed invention.

On the other hand, Roxane’s proposed construction of “concomitant” is faithful to the meaning that the inventor explicitly stated in the specification and provides the necessary clarity to the claim construction. For at least these reasons, the Court should adopt Roxane’s proposed construction set forth in Roxane’s opening brief.

II. ARGUMENT – The DDI Patents – “concomitant”

Jazz acknowledges that the inventor acted as its own lexicographer by providing a definition for “concomitant” in the ‘306 patent family specification. (*See* D.I. 84 at 10.) Jazz, however, improperly truncates that definition and adopts only a part of it as its proposed construction of “concomitant,” ignoring the inventor’s explicit construction when the two concomitantly administered drugs are GHB and valproate. The *Phillips* case that both parties have cited as authorizing an inventor to act as his own lexicographer most certainly does not tell us that a party may selectively cleave the inventor’s definition and omit its most salient aspects. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315-16 (Fed. Cir. 2005) (*en banc*). Yet that is what Jazz has done here. In the case of the two drugs being GHB and valproate, the inventor’s definition of “concomitant” accords a specific time period in which administration of valproate must occur when the first drug administered is GHB:

[t]hus, if the first drug is, e.g., Xyrem[®], or GHB, and the second drug is valproate, *the concomitant administration of the second drug occurs within two weeks, preferably within one week or even three days, before or after the administration of the first drug*

(‘306 patent at 8:41-45) (emphasis added).

Roxane’s proposed definition accurately captures the inventor’s *entire* definition of “concomitant,” including especially the portion that is devoted to the very two drugs identified in the claims—GHB and valproate. *See Prima Tek II v. Polypap*, 318 F.3d 1143, 1152 (Fed. Cir. 2003) (applicant’s definition for the term “band” includes *all words* following “as used herein, means...”).

Jazz’s purposely edited, litigation-contrived construction also is contrary to the goal of claim construction in the first place, which is to provide clarity to claim term meaning. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (“Claim construction is a

matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in determining infringement.”). Jazz’s construction provides no notice as to the scope of the claim term, which leaves the public without the ability to determine potential infringement or invalidity. *Id.* Does “operative” mean therapeutically operative and, if so, how much of a reduction in symptoms does that entail? Or does “operative” mean still causing a drug interaction, and if so, how is that measured and how much of a drug interaction? Jazz’s construction provides no clarity on these issues.

Thus, a rival company following Jazz’s definition would not know when or how to determine “if the effects of the first drug are still operative in the patient.” Jazz’s construction would therefore result in a moving target open to some later interpretation of how to measure the effects of a drug that would be at odds with the time period stated in the definition at column 8, lines 37-45 of the specification. *See PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1363 (Fed. Cir. 2005) (district court did not err in construing implicit time-dependent claim terms by limiting those terms to “technologies existing at the time of the invention”); *see also Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 386 (1996). In contrast, a competitor following Roxane’s proposed definition would know if its product contains a first drug administered within two weeks of a second drug.

Contrary to Jazz’s argument (*see* D.I. 84 at 11), Roxane’s proposed construction does not read in a preferred embodiment or specific example from the specification. Rather, Roxane’s proposed construction gives credit to the inventor’s complete lexicography, which is no less than the law demands.

Finally, Jazz’s objection to the term “single patient” in Roxane’s proposed construction is puzzling. (*See* D.I. 84 at 11.) Jazz’s proposed construction refers to “a patient.” Thus, both

parties' proposed constructions envision the two drugs being administered to one patient—whether it is construed as “a” patient or a “single” patent is a distinction without a difference.

III. CONCLUSION

For the foregoing reasons, Roxane respectfully requests the Court adopt Roxane's proposed construction.

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